

## SECTION 4

K 093871

### 4.0 510K (k) Summary of Safety and Effectiveness

APR 22 2010

**Trade Name:** Periophil  $\beta$  -TCP

**Common Name:** Synthetic Bone Graft Material

**Classification Name:** Bone Filling and Augmentation Material

**Official Contact Name:** Victor M. Bowers  
VP Medical Affairs

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**Date Prepared:** 12/14/2009

#### 4.1 Indication for Use

Periophil  $\beta$  -TCP is indicated for use as a bone grafting material to fill, augment, or reconstruct periodontal or oral/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Periophil  $\beta$  -TCP can be used with autogenous bone grafting materials. Typical uses include: periodontal/infrabony defects, ridge augmentation, extraction sites (implant preparation/placement), sinus lifts, and cystic cavities.

#### 4.2 Product Description

Periophil  $\beta$  -TCP is a bone graft substitute. Periophil  $\beta$  -TCP is a microporous and macroporous calcium phosphate ceramic consisting of beta tricalcium phosphate ( $\beta$ -TCP). Periophil  $\beta$  -TCP is available as granules and is provided sterile for single patient use.

Periophil  $\beta$  -TCP is a multidirectional interconnected porosity structure, similar to that of human cancellous bone. Periophil  $\beta$  -TCP slowly resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues. There is progressive resorption for 4 to 12 months (may vary patient to patient) of Periophil  $\beta$  -TCP resorbable bone filler.

#### 4.3 Substantial Equivalence

The following are the predicate devices that are substantially equivalent to Periophil  $\beta$ -TCP:

K063634 – RTR Syringe  
Septodont  
C/O Mr. Wayne H. Matelski  
Arent Fox, PLLC  
1050 Connecticut Avenue, NW  
Washington, District of Columbia 20036-5339

K051885 - MBCP™  
BIOMATLANTE  
ZA DES IV NATIONS  
5, rue Edouard Belin  
-F- 44360 VIGNEUX DE BRETAGNE  
France

K082917 – Mastergraft Resorbable Ceramic Granules  
Medtronic Sofamor Danek  
1800 Pyramid Place  
Memphis, TN 38132

#### **4.4 Biocompatibility Evaluations**

The biocompatibility of  $\beta$ -TCP is well documented. This biomaterial has consistently proven to be non-toxic, non-allergenic, biocompatible, and elicit no inflammation. No adverse effects or foreign body reactions have been reported. Periophil  $\beta$ -TCP utilizes identical materials to K063634 – RTR Syringe, and has the same type and duration of patient contact.

#### **4.5 Sterilization**

Periophil  $\beta$ -TCP is sterilized using gamma radiation. Processing is performed by Steris Isomedix Services, a contract sterilization company, cycle parameters were validated using an overkill methodology to  $10^{-6}$  SAL. Sterilization by the user is not required.

#### **4.6 Pre-Clinical Tests Performed**

Chemical safety of Periophil  $\beta$ -TCP is based on the recognized consensus standard specification ASTM F1088 "Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation". Periophil  $\beta$ -TCP conforms to the required specifications for heavy metal trace element levels.

#### 4.7 Risk Assessment

The primary risks with Periophil  $\beta$  -TCP have been identified through a risk assessment procedure in accordance with ISO 14971.

#### 4.8 Summary

In summary, Periophil  $\beta$  -TCP is substantially equivalent to the cited predicate devices. All have the same indication for use. Periophil  $\beta$  -TCP is indicated for use as a bone grafting material to fill, augment, or reconstruct periodontal or oral/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Periophil  $\beta$  -TCP can be used with autogenous bone grafting materials. Typical uses include: periodontal/infrabony defects, ridge augmentation, extraction sites (implant preparation/placement), sinus lifts, and cystic cavities.

The components used in Periophil  $\beta$  -TCP and the predicate devices are biocompatible, based on the history and use in many medical devices, peer reviewed literature, and from preclinical testing. Periophil  $\beta$  -TCP is substantially equivalent in indication for use, technical characteristics, and is as safe as the predicate device K063634 – RTR Syringe, Septodont, C/O Mr. Wayne H. Matelski, Arent Fox, PLLC, 1050 Connecticut Avenue, NW, Washington, District of Columbia 20036-5339.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

APR 22 2010

Mr. Victor M. Bowers  
Vice President Medical Affairs  
Cytophil, Incorporated  
2485 Corporate Circle, Unit 2  
East Troy, Wisconsin 53120

Re: K093871  
Trade/Device Name: Periophil  $\beta$ -TCP  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: LYC  
Dated: April 13, 2010  
Received: April 15, 2010

Dear Mr. Bowers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Anthony Watson', followed by the word 'for' in a smaller, cursive script.

Anthony Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## SECTION 2

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### 2.0 Indications for Use

510(k) Number: K093871

Device Name: Periophil  $\beta$  -TCP

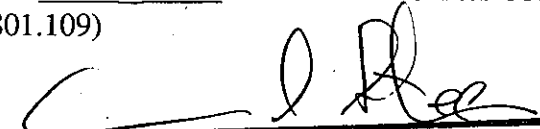
Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K093871